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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SIMS, JASON M	
ART UNIT	PAPER NUMBER
1631	
MAIL DATE	DELIVERY MODE
05/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,063	MARLOWE ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

MPEP section § 41.54 states that after decision by the Board, the proceeding will be returned to the examiner, subject to appellant's right of appeal or other review, for such further action by appellant or by the examiner, as the condition of the proceeding may require, to carry into effect the decision. For the Appeal No: 2008:3527, the Board has reversed the examiner wherein the decision was received 3/27/2009.

In the instant case, prosecution on the merits is being reopened as stated below in the instant Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-15 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Layne et al. (US P/N 5,968,731).

The instant claims are drawn to a computer-implemented method for preparing a binding-ready biological sample for a binding assay, comprising:

receiving a binding assay design for a binding assay;

preparing an experiment design for generating a binding-ready biological sample to be used in said binding assay;

choosing a robot method for generating said binding-ready biological sample;

generating work instructions for generating said binding-ready biological sample based on said experiment design and said robot method; and

executing said work instructions on robot stations to generate the binding-ready biological sample.

Layne et al. teach a system comprising process control tools (PCTs, which interface remote clients and the automated testing instruments), infectrons, and detectrons (where the infectrons and detectrons each is comprised of a group of interchangeable standard laboratory modules (SLMs) and standard support modules (SSMs) that perform the automated testing.) Layne et al. at col. 8, lines 15-30 teach that a remote client interfaced with a PCT is used to give a user/researcher access to the automated lab, wherein the user/research can define and perform the automated tests and to design experiments to be performed (lines 29-30). Layne et al. further teach at col. 8, lines 34-37 that the automated instruments perform the tests specified by the remote user. Thus Layne et al. teach receiving a binding assay design for a binding assay. Further, Layne et al. teach generating binding-ready biological sample (see col. 8, lines 24-26). In addition, Layne et al. teach that if the desired tests require submission of test specimens, the program control tools are used to define the requirements for packaging and labeling these specimens. As such, Layne et al. refer

to the SLMs and SSMs that prepare the assay as the infectron. Furthermore, Layne et al. at col. 12, lines 37-67 discuss components of the infectron, i.e. the viral cell inoculation SLM, incubation SLM, and cell washing SLM, which prepare the binding-ready biological sample. Layne et al. at col. 12, lines 37-67 further discuss a microtiter plate preparation SLM component that prepares the plate for the binding assay. Therefore the infectron and detectron, which act on instructions provided by the process controller, and indirectly a remote client user/researcher, read on the step of preparing an experiment design for generating a binding-ready biological sample to be used in said binding assay. Furthermore, the sample is considered a binding-ready biological sample because Layne et al. at col. 13, lines 21-24 teach that the sample prepared by the infectron will be used in an "enzyme-linked immuno-sorbent assay (ELISA)," which is a form of a binding assay. Layne et al. teach at col. 15, lines 5-15 that a remote client, wherein a user or researcher controls, may have a direct communication to the test instrument suite or may share information and instructions with the process controller. Layne et al. further teach at col. 15, lines 25-45 that the process controller receives test procedures defined by the remote client wherein the commands are then transformed into automated test suite commands, which define how the SSMs and SLMs, i.e. infectrons and detectrons, carry out their tasks, wherein the transformed designs into SLM commands reads on the step of generating work instructions for generating said binding-ready biological sample based on said experiment design and said robot method; and executing said work instructions on robot stations to generate the binding-ready biological sample. Layne et al. at col. 14, lines 50-53 teach that the

infectrons and detectrons contain standard laboratory modules that are removable and interchangeable, permitting easier maintenance and design improvements. Layne et al. teach at col. 12, lines 25-30 and col. 14, lines 33-35 examples of robots used as a component of the infectrons and detectrons, wherein the ability for selection of a particular module, i.e. robot, reads on the step of choosing a robot method for generating said binding-ready biological sample..

Layne et al. at col. 8, lines 28-30 teach that a user designs the experiments that are to be performed by the automated tester. Layne et al. at col.10, lines 33-43 teach that the system "allows researchers to design new experiments and offers the test designer specified degrees of freedom," which reads on the step of preparing an experiment design for generating a binding-ready biological sample to be used in said binding assay. Layne et al. at col. 11, lines 53-54 refer to a group of SLMs and SSMs an infectron, which carries out the automated testing.

Layne et al. at col. 9, lines 47-49 and lines 55-59 teach that the controllers of the automated testing optimize the sequences by which all tasks take place and are capable of dynamic retasking, which further enables optimization of performing experiments, thus anticipating claim 15.

Layne et al. at col. 13, lines 21-24 teach that the sample prepared by the infectron will be used in an "enzyme-linked immuno-sorbent assay (ELISA), which is a form of a binding assay that involves a hybridization as in claim 22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. (US P/N 5,968,731) as applied to claim 14 above and further in view of the following.

Layne et al. suggest, but do not explicitly teach a step of, before said generating, checking inventory for materials required for said experiment design.

Layne et al. suggest this because at col. 11, lines 22-26 and lines 58-59 they discuss a commerce PCT that interfaces with the SLMs, which implements functions related to "inventory management of test and support materials" and that materials for the automated testing may be obtained from the testing suite stock supplies. Therefore,

it is implied that before obtaining the materials from the suite stock supplies, that inventory of those supplies would have been checked.

Thus, It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have a system which performs automated testing based on user designs where the supplies may be obtained from the testing suite stock supplies as taught by Layne et al., but first performs a check for inventory of materials required for said experiment. This is because an automated system capable of said functionality as taught by Layne et al. would need to be able to notify the remote client/user that inventory was not available or the automated system it depended on for obtaining materials would fail. Therefore, the differences between the claimed invention and the prior art were encompassed in known variation or in a principal known. In addition, the differences are the product not of innovation, but of ordinary skill in the art and common sense.

Layne et al. suggest, but do not explicitly teach the limitations of claims 17-19 wherein the claims are drawn to further limitations of checking inventory by sending a inventory request to an inventory system, receiving inventory data indicating whether said materials are available in inventory, and ascertaining from said inventory data whether said materials are available in inventory.

Layen et al. suggest this because at col. 11, lines 22-26 and lines 58-59 they discuss a commerce PCT that interfaces with the SLMs, which implements functions related to "inventory management of test and support materials" and that materials for the automated testing may be obtained from the testing suite stock supplies. Therefore,

it is implied that before obtaining the materials from the suite stock supplies that inventory of those supplies would have been checked. Furthermore, Layen et al. teach an automated testing system, which performs the functions commanded by a user/researcher wherein the user/researcher is interfaced with the system via electronic communications. Therefore, it is further implied that an automated system would have set up communication functions to alert the user/researcher with updates throughout the procedure.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have a system which performs automated testing based on user designs where the supplies may be obtained from the testing suite stock supplies as taught by Layne et al., but first performs a check for inventory of materials by performing the limitations of claims 17-19, such as sending a inventory request to an inventory system. This is because an automated system capable of said functionality as taught by Layne et al. would want to be able to notify the remote client/user that inventory was not available or the automated system, if depended on for obtaining materials, would fail. Therefore, the differences between the claimed invention and the prior art are the product not of innovation, but of ordinary skill in the art and common sense.

Layne et al. suggest, but do not explicitly teach wherein said receiving further comprises acquiring a tissue sample.

Layne et al. suggest this because at col. 8, lines 30-32 that “if required, specimens are then packaged and physically transported to the automated lab site.” Layne et al. further teach at col. 11, lines 47-50 that the automated instrument suite for

performing the testing, can test biological samples, which comprises cells. Layne et al. further teach at col. 12 and 13 the testing instrument suite prepares the assay, which included preparing the sample.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have acquired a tissue sample wherein cells could have been extracted and prepared for the assay testing as taught by Layne et al. This is because the system taught by Layne et al. is directed to testing cell samples, which are often derived from tissue. Therefore, acquiring a tissue sample, from which a researcher will extract cells for performing an assay is the product not of innovation but of ordinary skill and common sense.

Layne et al. suggest, but do not explicitly teach the steps of extracting a constituent sample from said tissue sample; and updating inventory to include constituent sample as in claim 21.

Layne et al. suggest this because at col. 11, lines 66-67 and col. 12, lines 1-5 they teach that the infectron performs a number of operations including providing supply materials, pipetting, and storing samples wherein pipetting involves extracting a constituent sample from a biological sample and storing samples implies some type of registration or updating for the automated testing system.

It would have been obvious at the time of the instant invention to have extracted a constituent sample from a tissue sample and updated inventory to include said constituent sample in the automated testing system taught by Layne et al. This is because Layne et al. teach that the system is set up to extract constituent samples and

store inventory and supply inventory. Therefore to include a process that updates the inventory to include the constituent sample is a product not of innovation, but of ordinary skill and common sense. Moreover, Layne et al. teaching a system that extracts constituent samples and further teach that the different SLMs and SSMs are interchangeable to improve experimental design is implicitly capable of extracting constituent samples from a tissue sample with few interchangeable modifications. The differences between the claimed invention and prior art were encompassed in known variations as taught or in a principal known in the art as discussed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

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